U.S. District Court Southern District of New York (Foley Square) CIVIL DOCKET FOR CASE #: 1:17-cv-03960-JMF

Seife v. Food and Drug Administration et al Assigned to: Judge Jesse M. Furman

Referred to: Magistrate Judge James L. Cott (Settlement)

Cause: 05:552 Freedom of Information Act

ent) Nature of Suit: 895 Freedom of Information Act
Jurisdiction: Federal Question

Plaintiff

Charles Seife

represented by Cortelyou Churchill Kenney

Date Filed: 05/25/2017

Jury Demand: None

Cornell Law School First Amendment Clinic Myron Taylor Hall Ithaca, NY 14853 607–255–8897 Email: cortelyou.kenney@yale.edu LEAD ATTORNEY

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V.

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Intervenor Defendant

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Date Filed	#	Docket Text
05/25/2017	1	COMPLAINT against Food and Drug Administration, U.S. Department Of Health & Human Services. (Filing Fee \$ 400.00, Receipt Number 0208–13709202)Document filed by Charles Seife. (Attachments: # 1 Exhibit, # 2 Exhibit, # 3 Exhibit, # 4 Exhibit)(Schulz, David) (Entered: 05/25/2017)
05/25/2017	2	CIVIL COVER SHEET filed. (Schulz, David) (Entered: 05/25/2017)
05/25/2017	<u>3</u>	FILING ERROR – DEFICIENT SUMMONS REQUEST – PARTY NAME ERROR REQUEST FOR ISSUANCE OF SUMMONS as to Food and Drug Administration, re: 1 Complaint,. Document filed by Charles Seife. (Schulz, David) Modified on 5/26/2017 (kl). (Entered: 05/25/2017)
05/25/2017	4	FILING ERROR – DEFICIENT SUMMONS REQUEST – PARTY NAME ERROR REQUEST FOR ISSUANCE OF SUMMONS as to U.S. Department Of Health & Human Services, re: 1 Complaint,. Document filed by Charles Seife.

		(Schulz, David) Modified on 5/26/2017 (kl). (Entered: 05/25/2017)
05/25/2017	<u>5</u>	FILING ERROR – DEFICIENT SUMMONS REQUEST – PARTY NAME ERROR REQUEST FOR ISSUANCE OF SUMMONS as to U.S. Attorney General Jefferson Sessions, re: 1 Complaint,. Document filed by Charles Seife. (Schulz, David) Modified on 5/26/2017 (kl). (Entered: 05/25/2017)
05/25/2017	<u>6</u>	FILING ERROR – DEFICIENT SUMMONS REQUEST – PARTY NAME ERROR REQUEST FOR ISSUANCE OF SUMMONS as to Acting U.S. Attorney for the Southern District of New York Joon H. Kim, re: 1 Complaint,. Document filed by Charles Seife. (Schulz, David) Modified on 5/26/2017 (kl). (Entered: 05/25/2017)
05/26/2017		***NOTICE TO ATTORNEY REGARDING CASE OPENING STATISTICAL ERROR CORRECTION: Notice to attorney David A Schulz. The following case opening statistical information was erroneously selected/entered: County code Kings. The following correction(s) have been made to your case entry: the County code has been modified to New York. (kl) (Entered: 05/26/2017)
05/26/2017		***NOTICE TO ATTORNEY REGARDING PARTY MODIFICATION. Notice to attorney David A., Schulz. The party information for the following party/parties has been modified: U.S. Department Of Health & Human Services. The information for the party/parties has been modified for the following reason/reasons: party name contained a typographical error. (kl) (Entered: 05/26/2017)
05/26/2017		CASE OPENING INITIAL ASSIGNMENT NOTICE: The above–entitled action is assigned to Judge Jesse M. Furman. Please download and review the Individual Practices of the assigned District Judge, located at http://nysd.uscourts.gov/judges/District . Attorneys are responsible for providing courtesy copies to judges where their Individual Practices require such. Please download and review the ECF Rules and Instructions, located at http://nysd.uscourts.gov/ecf_filing.php . (kl) (Entered: 05/26/2017)
05/26/2017		Magistrate Judge Ronald L. Ellis is so designated. Pursuant to 28 U.S.C. Section 636(c) and Fed. R. Civ. P. 73(b)(1) parties are notified that they may consent to proceed before a United States Magistrate Judge. Parties who wish to consent may access the necessary form at the following link: http://nysd.uscourts.gov/forms.php . (kl) (Entered: 05/26/2017)
05/26/2017		Case Designated ECF. (kl) (Entered: 05/26/2017)
05/26/2017		***NOTICE TO ATTORNEY REGARDING DEFICIENT REQUEST FOR ISSUANCE OF SUMMONS. Notice to Attorney to RE-FILE Document No. 5 Request for Issuance of Summons, 4 Request for Issuance of Summons, 3 Request for Issuance of Summons. The filing is deficient for the following reason(s): PLEASE ENTER THE PARTY FIRST ON THE SUMMONS FORM. ALSO, JOON H. KIM AND JEFFERSON SESSIONS ARE NOT ENTERED ON ECF/INITIAL PLEADING. Re-file the document using the event type Request for Issuance of Summons found under the event list Service of Process – select the correct filer/filers – and attach the correct summons form PDF. (kl) (Entered: 05/26/2017)
05/26/2017	7	REQUEST FOR ISSUANCE OF SUMMONS as to Food and Drug Administration, re: 1 Complaint,. Document filed by Charles Seife. (Schulz, David) (Entered: 05/26/2017)
05/26/2017	8	FILING ERROR – DEFICIENT SUMMONS REQUEST – PARTY ERROR REQUEST FOR ISSUANCE OF SUMMONS as to U.S. Department Of Health & Human Services, re: 1 Complaint,. Document filed by Charles Seife. (Schulz, David) Modified on 5/30/2017 (kl). (Entered: 05/26/2017)
05/26/2017	9	NOTICE OF INITIAL PRETRIAL CONFERENCE: It is hereby ORDERED that counsel for all parties appear for an initial pretrial conference with the Court on July 11, 2017 at 4 p.m. in Courtroom 1105 of the Thurgood Marshall Courthouse, 40 Centre Street, New York, New York, and as further set forth herein. Initial Conference set for 7/11/2017 at 04:00 PM in Courtroom 1105, 40 Centre Street, New York, NY 10007 before Judge Jesse M. Furman. (Signed by Judge Jesse M. Furman on

		5/26/2017) (ras) (Entered: 05/26/2017)
05/30/2017	<u>10</u>	ELECTRONIC SUMMONS ISSUED as to Food and Drug Administration. (kl) (Entered: 05/30/2017)
05/30/2017		***NOTICE TO ATTORNEY REGARDING DEFICIENT REQUEST FOR ISSUANCE OF SUMMONS. Notice to Attorney to RE-FILE Document No. 8 Request for Issuance of Summons. The filing is deficient for the following reason(s): PARTY U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES IS NOT ENTERED ON ECF/PLEADING. Re-file the document using the event type Request for Issuance of Summons found under the event list Service of Process – select the correct filer/filers – and attach the correct summons form PDF. (kl) (Entered: 05/30/2017)
05/30/2017	<u>11</u>	FILING ERROR – DEFICIENT SUMMONS REQUEST – PARTY ERROR REQUEST FOR ISSUANCE OF SUMMONS as to U.S. Department Of Health & Human Services, re: 1 Complaint,. Document filed by Charles Seife. (Schulz, David) Modified on 5/31/2017 (kl). (Entered: 05/30/2017)
05/31/2017		***NOTICE TO ATTORNEY REGARDING DEFICIENT REQUEST FOR ISSUANCE OF SUMMONS. Notice to Attorney to RE-FILE Document No. 11 Request for Issuance of Summons. The filing is deficient for the following reason(s): PARTY U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES WAS NOT ENTERED ON ECF/INITIAL PLEADING. PLEASE ENTER THE PARTY EXACTLY AS IT APPEARS ON THE PLEADING. Re-file the document using the event type Request for Issuance of Summons found under the event list Service of Process – select the correct filer/filers – and attach the correct summons form PDF. (kl) (Entered: 05/31/2017)
05/31/2017	<u>12</u>	REQUEST FOR ISSUANCE OF SUMMONS as to Department Of Health and Human Services, re: 1 Complaint,. Document filed by Charles Seife. (Schulz, David) (Entered: 05/31/2017)
06/01/2017	<u>13</u>	ELECTRONIC SUMMONS ISSUED as to Department Of Health and Human Services. (pc) (Entered: 06/01/2017)
06/21/2017	<u>14</u>	AFFIDAVIT OF SERVICE. Department Of Health and Human Services served on 6/2/2017, answer due 6/23/2017; Food and Drug Administration served on 6/6/2017, answer due 6/27/2017. Service was made by MAIL. Document filed by Charles Seife. (Schulz, David) (Entered: 06/21/2017)
06/21/2017	<u>15</u>	MOTION for Partial Summary Judgment . Document filed by Charles Seife. Responses due by 7/5/2017 Return Date set for 7/12/2017 at 11:12 PM.(Schulz, David) (Entered: 06/21/2017)
06/21/2017	<u>16</u>	MEMORANDUM OF LAW in Support re: 15 MOTION for Partial Summary Judgment . Document filed by Charles Seife. (Attachments: #1 Declaration of Plaintiff Charles Seife, #2 Declaration of Cortelyou Kenney, #3 Exhibit A, #4 Exhibit B, #5 Exhibit C, #6 Exhibit D, #7 Exhibit E, #8 Exhibit F, #9 Exhibit G, #10 Exhibit H, #11 Exhibit I, #12 Exhibit J, #13 Exhibit K, #14 Exhibit L, #15 Exhibit M, #16 Exhibit N, #17 Exhibit O, #18 Exhibit P, #19 Exhibit Q, #20 Exhibit R)(Schulz, David) (Entered: 06/21/2017)
06/22/2017	<u>17</u>	RULE 56.1 STATEMENT. Document filed by Charles Seife. (Schulz, David) (Entered: 06/22/2017)
06/22/2017	<u>18</u>	NOTICE OF APPEARANCE by Dominika Natalia Tarczynska on behalf of Department Of Health and Human Services, Food and Drug Administration. (Tarczynska, Dominika) (Entered: 06/22/2017)
06/22/2017	19	ORDER with respect to <u>15</u> Motion for Partial Summary Judgment. The parties shall appear for a conference with the Court on Tuesday, June 27, 2017, at 3:45 p.m. Counsel shall confer in advance of the conference with respect to a briefing schedule for Plaintiff's motion and any other matters they believe should be addressed at the conference. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 06/22/2017)

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06/22/2017	<u>20</u>	DECLARATION of Cortelyou Kenney in Support re: <u>15</u> MOTION for Partial Summary Judgment Document filed by Charles Seife. (Schulz, David) (Entered: 06/22/2017)
06/23/2017	<u>21</u>	CONSENT LETTER MOTION to Adjourn Conference <i>scheduled for June 27, 2017</i> addressed to Judge Jesse M. Furman from Dominika Tarczynska dated June 23, 2017. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 06/23/2017)
06/25/2017	22	ORDER granting <u>21</u> Letter Motion to Adjourn Conference scheduled for June 27, 2017. The Court will address the pending motion at the July 11, 2017 conference. Unless and until the Court orders otherwise, further briefing on the pending motion is suspended. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 06/25/2017)
07/05/2017	<u>23</u>	ANSWER to 1 Complaint,. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 07/05/2017)
07/06/2017	24	SCHEDULING ORDER: The time of the initial pretrial conference scheduled for July 11, 2017, is CHANGED to 3:15 p.m. The parties are reminded that, per the Notice of Initial Pretrial Conference, they are required to submit a joint letter (and, if appropriate, a proposed Case Management Plan) no later than today. (Signed by Judge Jesse M. Furman on 7/6/2017) (Furman, Jesse) (Entered: 07/06/2017)
07/06/2017	<u>25</u>	JOINT LETTER addressed to Judge Jesse M. Furman from Dominika Tarczynska & David A. Schulz dated July 6, 2017 re: Joint Letter in Advance of Initial Conference. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 07/06/2017)
07/10/2017	<u>26</u>	JOINT LETTER addressed to Judge Jesse M. Furman from Dominika Tarczynska & David A. Schulz dated July 10, 2017 re: Status of Parties' Discussions Regarding Production Schedule. Document filed by Department Of Health and Human Services, Food and Drug Administration. (Attachments: # 1 Exhibit A: Defendants' Proposed Production Schedule, # 2 Plaintiff's Second Narrowed FOIA Request, # 3 Plaintiff's Second Prioritization and Production Schedule)(Tarczynska, Dominika) (Entered: 07/10/2017)
07/10/2017	<u>27</u>	FILING ERROR – DEFICIENT DOCKET ENTRY – MOTION for Cortelyou Churchill Kenney to Appear Pro Hac Vice . Motion and supporting papers to be reviewed by Clerk's Office staff. Document filed by Charles Seife. (Attachments: # 1 Text of Proposed Order, # 2 Affidavit Declaration of Cortelyou Kenney in Support of Motion Pro Hac Vice, # 3 Exhibit Certificate of Good Standing California, # 4 Exhibit Certificate of Good Standing District of Columbia, # 5 Exhibit Certificate of Good Standing New York)(Kenney, Cortelyou) Modified on 7/11/2017 (wb). (Entered: 07/10/2017)
07/11/2017		>>>NOTICE REGARDING DEFICIENT MOTION TO APPEAR PRO HAC VICE. Notice to RE-FILE re: Document No. 27 MOTION for Cortelyou Churchill Kenney to Appear Pro Hac Vice. Motion and supporting papers to be reviewed by Clerk's Office staff The filing is deficient for the following reason(s): missing Certificate of Good Standing from Supreme Court of California; the filing fee was not paid;. Re-file the motion as a Motion to Appear Pro Hac Vice – attach the correct signed PDF – select the correct named filer/filers – attach valid Certificates of Good Standing issued within the past 30 days – attach Proposed Order. Pay the filing fee using the event Pro Hac Vice Fee Payment found under the event list Other Documents. (wb) (Entered: 07/11/2017)
07/11/2017	<u>28</u>	NOTICE OF APPEARANCE by Margaret Elanor McCarthy on behalf of Charles Seife. (McCarthy, Margaret) (Entered: 07/11/2017)
07/11/2017	29	ORDER with respect to 15 Motion for Partial Summary Judgment. As discussed on the record at the conference held earlier today, Defendants are ordered to produce the "Email and memo from John Jenkins to Robert Califf, dated Sept. 14, 2016, sent at 5:36 PM, subject 'Memo'" no later than July 24, 2017. Moreover, Defendants shall file any opposition to Plaintiff's motion for partial summary judgment by July 31, 2017. Plaintiff will then have until August 7, 2017 to file a reply. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 07/11/2017)

07/11/2017		NOTICE of Hearing: Settlement Conference set for 7/14/2017 at 11:00 AM in Courtroom 11C, 500 Pearl Street, New York, NY 10007 before Magistrate Judge Ronald L. Ellis. All counsel must be present and have e–filed a notice of appearance on the ECF system prior to the conference. Unless excused by the Court, each party, together with counsel, must appear in person for the conference. Any party appearing for the settlement conference must have FULL AUTHORITY TO SETTLE THE CASE. If a party is not prepared to go forward with settlement discussions, written notice to the Court is required prior to the conference. No request for adjournment will be considered unless made at least THREE BUSINESS DAYS before the scheduled conference and only after the parties have consulted with each other. Direct inquiries to Rupa Shah (212)–805–0242. (rsh) (Entered: 07/11/2017)
07/11/2017		Minute Entry for proceedings held before Judge Jesse M. Furman: Initial Pretrial Conference held on 7/11/2017. Cortelyou Jenney and Margaret McCarthy present for Plaintiff. Dominika Tarczynska present for Defendants. Court reporter present. (ab) (Entered: 07/26/2017)
07/12/2017	<u>30</u>	ORDER REFERRING CASE TO MAGISTRATE JUDGE. Order that case be referred to the Clerk of Court for assignment to a Magistrate Judge for Settlement. Referred to Magistrate Judge Ronald L. Ellis. SO ORDERED. (Signed by Judge Jesse M. Furman on 7/11/17) (yv) (Entered: 07/12/2017)
07/12/2017	<u>31</u>	SECOND MOTION for Cortelyou Churchill Kenney to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–13888610. Motion and supporting papers to be reviewed by Clerk's Office staff. Document filed by Charles Seife. (Attachments: # 1 Declaration of Cortelyou C. Kenney in Support of Motion to Appear Pro Hac Vice, # 2 Text of Proposed Order, # 3 Certificate of Good Standing NY, # 4 Certificate of Good Standing CA Supreme Court, # 5 Certificate of Good Standing DC)(Kenney, Cortelyou) (Entered: 07/12/2017)
07/12/2017		>>>NOTICE REGARDING PRO HAC VICE MOTION. Regarding Document No. 31 SECOND MOTION for Cortelyou Churchill Kenney to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–13888610. Motion and supporting papers to be reviewed by Clerk's Office staff The document has been reviewed and there are no deficiencies. (jc) (Entered: 07/12/2017)
07/12/2017	32	ORDER granting 31 Motion for Cortelyou Churchill Kenney to Appear Pro Hac Vice (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 07/12/2017)
07/13/2017	<u>33</u>	CONSENT LETTER MOTION for Conference re: Notice of Hearing,,, <i>Seeking Permission for Agency Counsel to Appear Telephonically At Settlement Conference</i> addressed to Magistrate Judge Ronald L. Ellis from Dominika Tarczynska dated July 13, 2017. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 07/13/2017)
07/13/2017	34	ORDER granting <u>33</u> Letter Motion for Conference. (HEREBY ORDERED by Magistrate Judge Ronald L. Ellis)(Text Only Order) (Ellis, Ronald) (Entered: 07/13/2017)
07/13/2017	<u>35</u>	FILING ERROR – ELECTRONIC FILING FOR NON–ECF DOCUMENT – MOTION for Leave to Appear Darius Fullmer, Law Student Intern . Document filed by Charles Seife.(Schulz, David) Modified on 9/5/2017 (ldi). (Entered: 07/13/2017)
07/14/2017		Minute entry for proceedings held before Magistrate Judge Ronald L. Ellis: Settlemen Conference held on 7/14/2017 at 11:15 a.m. (rsh) (Entered: 07/14/2017)
07/14/2017	<u>36</u>	MEMO ENDORSEMENT granting <u>35</u> Motion for Leave to Appear. ENDORSEMENT: So ordered. (Signed by Judge Jesse M. Furman on 7/14/2017) (ras Modified on 7/19/2017 (ras). (Entered: 07/14/2017)
07/19/2017	<u>37</u>	JOINT LETTER MOTION for Conference addressed to Magistrate Judge Ronald L. Ellis from Dominika Tarczynska and Cortelyou Kenney dated July 19, 2017. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 07/19/2017)
07/19/2017	38	ORDER granting <u>37</u> Letter Motion for Conference. Telephone Conference set for 7/20/2017 at 5:00 PM before Magistrate Judge Ronald L. Ellis. On the day of the

		conference, the Parties will jointly place a telephone call to the chambers of Judge Ronald L. Ellis, at 212–805–0563. Upon receipt of this order, if you need further information, direct inquiries to Rupa Shah, 212–805–0242. (HEREBY ORDERED by Magistrate Judge Ronald L. Ellis)(Text Only Order) (Ellis, Ronald) (Entered: 07/19/2017)
07/20/2017		Minute entry for proceedings held before Magistrate Judge Ronald L. Ellis: Telephone Conference held on 7/20/2017 at 5:30 p.m. (rsh) (Entered: 07/21/2017)
07/24/2017		NOTICE of Hearing: Telephone Conference set for 7/24/2017 at 3:30 PM before Magistrate Judge Ronald L. Ellis. On the day of the conference, the Parties will jointly place a telephone call to the chambers of Judge Ronald L. Ellis, at 212–805–0563. Upon receipt of this order, if you need further information, direct inquiries to Rupa Shah, 212–805–0242.(rsh) (Entered: 07/24/2017)
07/24/2017		Minute entry for proceedings held before Magistrate Judge Ronald L. Ellis: Telephone Conference held on 7/24/2017 at 3:30 p.m. (rsh) (Entered: 07/24/2017)
07/27/2017	<u>39</u>	STIPULATION AND ORDER: NOW, THEREFORE, IT IS HEREBY STIPULATED AND AGREED, by and between the Parties and their counsel, that: On July 24, 2017, the FDA produced non–exempt portions 1 of "The Chronology prepared by Virginia Behr and submitted to the Scientific Dispute Resolution Board regarding eteplirsen ("Behr Chronology")," and "Email and memo from John Jenkins to Robert Califf, dated Sept. 14, 2016, sent at 5:36 PM, subject "Memo." Beginning on August 17, 2017, the FDA will make rolling bi—weekly productions of documents with production to be completed in accordance with the schedule set forth below. In the event FDA is unable to complete its production on the dates outlined above or other disputes arise between the Parties, the Parties will in good faith attempt to reach agreement and either the Parties will jointly advise the Court of any modification of this Stipulation or either Party may present the disputed issue to Magistrate Judge Ellis for resolution. Upon entry of this Stipulation and Order, but no later than July 31, 2017, Plaintiff will voluntary withdraw his motion for partial summary judgment challenging Defendants' denial of Plaintiff's request for expedited processing of his FOIA request, ECF No. 16. The Clerk of Court is directed to close this case. All motions are moot. All conferences are cancelled. The Court retains jurisdiction to enforce the terms of this Stipulation and Order and to adjudicate any disputes in connection with it, and as further set forth in this order. (Signed by Judge Jesse M. Furman on 7/27/2017) (ap) (Entered: 07/27/2017)
07/28/2017	<u>40</u>	LETTER MOTION to Reopen Case addressed to Judge Jesse M. Furman from Charles Seife dated July 28, 2017. Document filed by Charles Seife.(Kenney, Cortelyou) (Entered: 07/28/2017)
07/28/2017	<u>41</u>	ORDER granting <u>40</u> Letter Motion to Reopen Case. Application GRANTED. The Clerk of Court is directed to reopen this case. SO ORDERED. (Signed by Judge Jesse M. Furman on 7/28/2017) (ras) (Entered: 07/28/2017)
07/31/2017	42	ORDER: The parties shall submit a joint letter by November 1, 2017, updating the Court on Defendants' progress in meeting their disclosure obligations as set forth in the Stipulation and Order. In addition, the parties shall appear for a conference with the Court on December 11, 2017 at 3 p.m. in Courtroom 1105 of the Thurgood Marshall Courthouse, 40 Centre Street, New York, New York. Finally, the parties shall submit another joint letter, no later than the Thursday of the week prior to the conference, updating the Court on issues to address at the conference and the next steps in the litigation. (Status Conference set for 12/11/2017 at 03:00 PM in Courtroom 1105, 40 Centre Street, New York, NY 10007 before Judge Jesse M. Furman.) (Signed by Judge Jesse M. Furman on 7/31/2017) (ras) (Entered: 07/31/2017)
09/15/2017	<u>43</u>	MOTION to Intervene . Document filed by Sarepta Therapeutics, Inc. (Attachments: # 1 Text of Proposed Order, # 2 Proposed Answer)(Bernstein, Daniel) (Entered: 09/15/2017)
09/15/2017	<u>44</u>	MEMORANDUM OF LAW in Support re: <u>43</u> MOTION to Intervene Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 09/15/2017)
09/15/2017	<u>45</u>	RULE 7.1 CORPORATE DISCLOSURE STATEMENT. No Corporate Parent. Document filed by Sarepta Therapeutics, Inc.(Bernstein, Daniel) (Entered:

		09/15/2017)
09/15/2017	<u>46</u>	NOTICE OF APPEARANCE by Daniel Bernstein on behalf of Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 09/15/2017)
09/18/2017	<u>47</u>	ORDER granting 43 Motion to Intervene. Upon consideration of Sarepta's unopposed Motion to Intervene (the "Motion") and the record of this case, it is this 18th day of September, 2017 hereby ORDERED that the Motion is granted. The Clerk of Court is directed to terminate Docket No. 43. (Signed by Judge Jesse M. Furman on 9/18/2017) (ras) (Entered: 09/18/2017)
09/19/2017	<u>48</u>	ANSWER to <u>1</u> Complaint,. Document filed by Sarepta Therapeutics, Inc.(Bernstein, Daniel) (Entered: 09/19/2017)
11/01/2017	<u>49</u>	JOINT LETTER addressed to Judge Jesse M. Furman from Dominika Tarczynska, Cortelyou Kenney & Daniel R. Bernstein dated November 1, 2017 re: Status. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 11/01/2017)
11/09/2017	<u>50</u>	FILING ERROR – DEFICIENT DOCKET ENTRY – MOTION for Kristen E. Ittig to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–14346512. Motion and supporting papers to be reviewed by Clerk's Office staff. Document filed by Sarepta Therapeutics, Inc. (Attachments: # 1 Text of Proposed Order, # 2 Declaration in Support, # 3 DC Cert of Good Standing, # 4 MD Cert of Good Standing, # 5 VA Cert of Good Standing)(Ittig, Kristen) Modified on 11/13/2017 (wb) (Entered: 11/09/2017)
11/09/2017	<u>51</u>	FILING ERROR – DEFICIENT DOCKET ENTRY – MOTION for Stuart W. Turner to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–14346613. Motion and supporting papers to be reviewed by Clerk's Office staff. Document filed by Sarepta Therapeutics, Inc. (Attachments: # 1 Text of Proposed Order, # 2 Declaration in Support, # 3 DC Cert of Good Standing, # 4 VA Cert of Good Standing)(Turner, Stuart) Modified on 11/13/2017 (wb). (Entered: 11/09/2017)
11/09/2017	<u>52</u>	FILING ERROR – DEFICIENT DOCKET ENTRY – MOTION for Amanda J. Sherwood to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–14346716. Motion and supporting papers to be reviewed by Clerk's Office staff. Document filed by Sarepta Therapeutics, Inc. (Attachments: # 1 Text of Proposed Order, # 2 Declaration in Support, # 2 DC Cert of Good Standing, # 4 VA Cert of Good Standing)(Sherwood, Amanda) Modified on 11/13/2017 (wb). (Entered: 11/09/2017)
11/13/2017		>>>NOTICE REGARDING DEFICIENT MOTION TO APPEAR PRO HAC VICE. Notice to RE-FILE Document No. 50 MOTION for Kristen E. Ittig to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–14346512. Motion and supporting papers to be reviewed by Clerk's Office staff., 52 MOTION for Amanda J. Sherwood to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–14346716. Motion and supporting papers to be reviewed by Clerk's Office staff., 51 MOTION for Stuart W. Turner to Appear Pro Hac Vice Filing fee \$ 200.00, receipt number 0208–14346613. Motion and supporting papers to be reviewed by Clerk's Office staff The filing is deficient for the following reason(s): missing Certificate of Good Standing from Supreme Court o Virginia;. Re–file the motion as a Motion to Appear Pro Hac Vice – attach the correct signed PDF – select the correct named filer/filers – attach valid Certificates of Good Standing issued within the past 30 days – attach Proposed Order (wb) (Entered: 11/13/2017)
11/16/2017	<u>53</u>	MOTION for Kristen E. Ittig to Appear Pro Hac Vice <i>Filing fee \$ 200.00, receipt number 0208–14346512</i> Motion and supporting papers to be reviewed by Clerk' Office staff. Document filed by Sarepta Therapeutics, Inc. (Attachments: # 1 Text of Proposed Order, # 2 Declaration in Support, # 3 DC Cert of Good Standing, # 4 MD Cert of Good Standing, # 5 VA Cert of Good Standing)(Ittig, Kristen) (Entered: 11/16/2017)
11/16/2017	<u>54</u>	MOTION for Stuart W. Turner to Appear Pro Hac Vice <i>Filing fee \$ 200.00</i> , <i>receipt number 0208–14346613</i> . Motion and supporting papers to be reviewed by Clerk's Office staff. Document filed by Sarepta Therapeutics, Inc. (Attachments: # 1 Text of

		Proposed Order, # 2 Declaration in Support, # 3 Declaration in Support of Motion, # 4 VA Cert of Good Standing)(Turner, Stuart) (Entered: 11/16/2017)
11/16/2017		>>>NOTICE REGARDING PRO HAC VICE MOTION. Regarding Document No. 53 MOTION for Kristen E. Ittig to Appear Pro Hac Vice Filing fee \$ 200.00, receipt number 0208–14346512 Motion and supporting papers to be reviewed by Clerk's Office staff., 54 MOTION for Stuart W. Turner to Appear Pro Hac Vice Filing fee \$ 200.00, receipt number 0208–14346613. Motion and supporting papers to be reviewed by Clerk's Office staff The document has been reviewed and there are no deficiencies. (wb) (Entered: 11/16/2017)
11/16/2017	<u>55</u>	MOTION for Amanda J. Sherwood to Appear Pro Hac Vice <i>Filing fee \$ 200.00</i> , receipt number 0208–14346716. Motion and supporting papers to be reviewed by Clerk's Office staff. Document filed by Sarepta Therapeutics, Inc. (Attachments: # 1 Text of Proposed Order, # 2 Declaration in Support, # 3 DC Cert of Good Standing, # 4 VA Cert of Good Standing)(Sherwood, Amanda) (Entered: 11/16/2017)
11/16/2017		>>>NOTICE REGARDING PRO HAC VICE MOTION. Regarding Document No. 55 MOTION for Amanda J. Sherwood to Appear Pro Hac Vice Filing fee \$ 200.00, receipt number 0208–14346716. Motion and supporting papers to be reviewed by Clerk's Office staff The document has been reviewed and there are no deficiencies. (wb) (Entered: 11/16/2017)
11/16/2017	56	ORDER granting <u>53</u> , <u>54</u> , and <u>55</u> Motions for Kristen E. Ittig, Stuart W. Turner, and Amanda J. Sherwood to Appear Pro Hac Vice. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 11/16/2017)
12/01/2017	<u>57</u>	JOINT LETTER MOTION to Continue <i>December 11 status conference</i> addressed to Judge Jesse M. Furman dated 12/1/2017. Document filed by Charles Seife.(Kenney, Cortelyou) (Entered: 12/01/2017)
12/02/2017		Magistrate Judge Stewart A. Aaron is so redesignated. (ad) (Entered: 12/02/2017)
12/02/2017		NOTICE OF REDESIGNATION TO ANOTHER MAGISTRATE JUDGE. The above entitled action has been redesignated to Magistrate Judge Stewart D. Aaron. Please note that this is a reassignment of the designation only. (ad) (Entered: 12/02/2017)
12/04/2017		NOTICE OF REASSIGNMENT OF A REFERRAL TO ANOTHER MAGISTRATE JUDGE. The referral in the above entitled action has been reassigned to Magistrate Judge Stewart D. Aaron, for Settlement. Magistrate Judge Ronald L. Ellis no longer referred to the case. (ad) (Entered: 12/04/2017)
12/04/2017		Magistrate Judge James L. Cott is so redesignated. (ad) (Entered: 12/04/2017)
12/04/2017		NOTICE OF REASSIGNMENT OF A REFERRAL TO ANOTHER MAGISTRATE JUDGE. The referral in the above entitled action has been reassigned to Magistrate Judge James L. Cott, for Settlement. Magistrate Judge Stewart D. Aaron no longer referred to the case. (ad) (Entered: 12/04/2017)
12/04/2017	58	ORDER granting <u>57</u> Letter Motion to Continue. The pretrial conference is adjourned to January 22, 2018, at 3:45 p.m. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 12/04/2017)
01/10/2018	<u>59</u>	MOTION for Thomas S. Leatherbury to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–14560139. Motion and supporting papers to be reviewed by Clerk's Office staff. Document filed by Charles Seife. (Attachments: # 1 Affidavit Ex. 1 – Affidavit of Thomas S. Leatherbury in Support of Motion For Admission Pro Hac Vice, # 2 Exhibit Ex. 2 – Certificate of Good Standing, # 3 Text of Proposed Order Ex. 3 – Proposed Order for Admission Pro Hac Vice)(Leatherbury, Thomas) (Entered: 01/10/2018)
01/10/2018		>>>NOTICE REGARDING PRO HAC VICE MOTION. Regarding Document No. <u>59</u> MOTION for Thomas S. Leatherbury to Appear Pro Hac Vice. Filing fee \$ 200.00, receipt number 0208–14560139. Motion and supporting papers to be reviewed by Clerk's Office staff The document has been reviewed and there are no deficiencies. (bcu) (Entered: 01/10/2018)

01/10/2018	60	ORDER granting <u>59</u> Motion for Thomas S. Leatherbury to Appear Pro Hac Vice. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 01/10/2018)
01/11/2018	<u>61</u>	LETTER MOTION to Adjourn Conference addressed to Judge Jesse M. Furman from Daniel R. Bernstein dated January 11, 2018. Document filed by Sarepta Therapeutics, Inc. Return Date set for 1/24/2018 at 03:45 PM.(Bernstein, Daniel) (Entered: 01/11/2018)
01/12/2018	62	ORDER granting <u>61</u> Letter Motion to Adjourn Conference. The pretrial conference is adjourned to January 24, 2018, at 3:30 p.m. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 01/12/2018)
01/18/2018	<u>63</u>	JOINT LETTER addressed to Judge Jesse M. Furman from Dominika Tarczynska, Cortelyou Kenney & Daniel R. Bernstein dated January 18, 2017 re: Proposed Summary Judgment Briefing Schedule. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 01/18/2018)
01/19/2018	64	ORDER re: <u>63</u> Letter, filed by Department Of Health and Human Services, Food and Drug Administration. The parties' proposed briefing schedule is hereby adopted. In light of that, the conference scheduled for January 24, 2018, is CANCELLED. SO ORDERED. (Signed by Judge Jesse M. Furman on 1/19/2018) (Text Only Order) (Furman, Jesse) (Entered: 01/19/2018)
03/22/2018	<u>65</u>	JOINT LETTER addressed to Judge Jesse M. Furman from Dominika Tarczynska, Cortelyou Kenney & Kristen Ittig dated March 22, 2018 re: Issues to Be Addressed in Cross Motions for Summary Judgment. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 03/22/2018)
03/23/2018	<u>66</u>	MEMO ENDORSEMENT on re: <u>65</u> Letter, filed by Department Of Health and Human Services, Food and Drug Administration. ENDORSEMENT: SO ORDERED. (Signed by Judge Jesse M. Furman on 3/23/2018) (ras) (Entered: 03/23/2018)
03/27/2018	<u>67</u>	MOTION for Daniel L. Tobey to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–14863976. Motion and supporting papers to be reviewed by Clerk's Office staff. Document filed by Charles Seife. (Attachments: # 1 Affidavit Ex. 1 – Affidavit of Daniel L. Tobey in Support of Motion for Admission Pro Hac Vice, # 2 Exhibit Ex. 2 – Certificate of Good Standing, # 3 Text of Proposed Order Proposed Order For Admission Pro Hac Vice)(Tobey, Daniel) (Entered: 03/27/2018)
03/27/2018		>>>NOTICE REGARDING PRO HAC VICE MOTION. Regarding Document No. 67 MOTION for Daniel L. Tobey to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–14863976. Motion and supporting papers to be reviewed by Clerk's Office staff The document has been reviewed and there are no deficiencies. (ma) (Entered: 03/27/2018)
03/27/2018	68	ORDER granting <u>67</u> Motion for Daniel L. Tobey to Appear Pro Hac Vice (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 03/27/2018)
04/06/2018	<u>69</u>	MOTION for Summary Judgment . Document filed by Sarepta Therapeutics, Inc.(Bernstein, Daniel) (Entered: 04/06/2018)
04/06/2018	<u>70</u>	MEMORANDUM OF LAW in Support re: <u>69</u> MOTION for Summary Judgment Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 04/06/2018)
04/06/2018	<u>71</u>	RULE 56.1 STATEMENT. Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 04/06/2018)
04/06/2018	<u>72</u>	DECLARATION of Ian Estepan in Support re: <u>69</u> MOTION for Summary Judgment Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 04/06/2018)
04/06/2018	<u>73</u>	DECLARATION of Kristen E. Ittig in Support re: <u>69</u> MOTION for Summary Judgment Document filed by Sarepta Therapeutics, Inc. (Attachments: # <u>1</u> Exhibit A, # <u>2</u> Exhibit B)(Bernstein, Daniel) (Entered: 04/06/2018)

04/06/2018	<u>74</u>	MOTION for Summary Judgment . Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 04/06/2018)
04/06/2018	<u>75</u>	MEMORANDUM OF LAW in Support re: 74 MOTION for Summary Judgment Document filed by Department Of Health and Human Services, Food and Drug Administration. (Tarczynska, Dominika) (Entered: 04/06/2018)
04/06/2018	<u>76</u>	DECLARATION of Sarah Kotler in Support re: 74 MOTION for Summary Judgment Document filed by Department Of Health and Human Services, Food and Drug Administration. (Attachments: # 1 Exhibit A)(Tarczynska, Dominika) (Entered: 04/06/2018)
04/06/2018	<u>77</u>	DECLARATION of Nancy B. Sager in Support re: 74 MOTION for Summary Judgment Document filed by Department Of Health and Human Services, Food and Drug Administration. (Attachments: #1 Exhibit A, #2 Exhibit B, #3 Exhibit C, #4 Exhibit D, #5 Exhibit E, #6 Exhibit F, #7 Exhibit G, #8 Exhibit H, #9 Exhibit I, #10 Exhibit J, #11 Exhibit K, #12 Exhibit L, #13 Exhibit M, #14 Exhibit N, #15 Exhibit O)(Tarczynska, Dominika) (Entered: 04/06/2018)
04/10/2018	<u>78</u>	MEMORANDUM OF LAW in Support re: <u>69</u> MOTION for Summary Judgment . <i>This document replaces DKT # 70</i> . Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 04/10/2018)
05/16/2018	<u>79</u>	FIRST LETTER MOTION for Extension of Time addressed to Judge Jesse M. Furman from Charles Seife dated 05/08/2018. Document filed by Charles Seife.(Kenney, Cortelyou) (Entered: 05/16/2018)
05/16/2018	80	ORDER granting <u>79</u> Letter Motion for Extension of Time. Plaintiff's request for an extension of time to file for summary judgment is GRANTED. The deadline is now May 29, 2018. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 05/16/2018)
05/21/2018	<u>81</u>	NOTICE OF APPEARANCE by Devon Charles Holstad on behalf of Charles Seife. (Holstad, Devon) (Entered: 05/21/2018)
05/24/2018	<u>82</u>	NOTICE OF APPEARANCE by Sarah Catherine Curl Tishler on behalf of Charles Seife. (Tishler, Sarah) (Entered: 05/24/2018)
05/25/2018	<u>83</u>	MOTION for Jean Hee Kim to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–15119162. Motion and supporting papers to be reviewed by Clerk's Office staff. Document filed by Charles Seife. (Attachments: # 1 Affidavit Declaration in Support of Jean Hee Kim's Motion for Admission Pro Hac Vice, # 2 Text of Proposed Order, # 3 Certificate of Good Standing CA Supreme Court)(Kim, Jean Hee) (Entered: 05/25/2018)
05/25/2018		>>>NOTICE REGARDING PRO HAC VICE MOTION. Regarding Document No. 83 MOTION for Jean Hee Kim to Appear Pro Hac Vice . Filing fee \$ 200.00, receipt number 0208–15119162. Motion and supporting papers to be reviewed by Clerk's Office staff The document has been reviewed and there are no deficiencies. (wb) (Entered: 05/25/2018)
05/26/2018	84	ORDER granting <u>83</u> Motion for Jean Hee Kim to Appear Pro Hac Vice (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 05/26/2018)
05/29/2018	<u>85</u>	CROSS MOTION for Summary Judgment . Document filed by Charles Seife.(Kenney, Cortelyou) (Entered: 05/29/2018)
05/29/2018	<u>86</u>	MEMORANDUM OF LAW in Support re: <u>85</u> CROSS MOTION for Summary Judgment . <i>and in Opposition to Defendants' Motions for Summary Judgment</i> . Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 05/29/2018)
05/29/2018	<u>87</u>	DECLARATION of Charles Seife in Support re: <u>85</u> CROSS MOTION for Summary Judgment Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 05/29/2018)
05/29/2018	<u>88</u>	DECLARATION of Dr. Peter Lurie in Support re: <u>85</u> CROSS MOTION for Summary Judgment Document filed by Charles Seife. (Kenney, Cortelyou) (Entered:

		05/29/2018)
05/29/2018	<u>89</u>	DECLARATION of Dr. Diana Zuckerman in Support re: <u>85</u> CROSS MOTION for Summary Judgment Document filed by Charles Seife. (Kenney, Cortelyou) (Entered 05/29/2018)
05/29/2018	90	DECLARATION of Cortelyou Kenney, Esq. in Support re: <u>85</u> CROSS MOTION for Summary Judgment Document filed by Charles Seife. (Attachments: # <u>1</u> Exhibit A, # <u>2</u> Exhibit B, # <u>3</u> Exhibit C, # <u>4</u> Exhibit D, # <u>5</u> Exhibit E, # <u>6</u> Exhibit F, # <u>7</u> Exhibit C # <u>8</u> Exhibit H, # <u>9</u> Exhibit I, # <u>10</u> Exhibit J, # <u>11</u> Exhibit K, # <u>12</u> Exhibit L, # <u>13</u> Exhibit M, # <u>14</u> Exhibit N, # <u>15</u> Exhibit O, # <u>16</u> Exhibit P, # <u>17</u> Exhibit Q, # <u>18</u> Exhibit R, # <u>19</u> Exhibit S, # <u>20</u> Exhibit T, # <u>21</u> Exhibit U, # <u>22</u> Exhibit V, # <u>23</u> Exhibit W, # <u>24</u> Exhibit X – Part 1 (pages 1–90), # <u>25</u> Exhibit X – Part 2 (pages 91–188), # <u>2</u> Exhibit Y, # <u>27</u> Exhibit Z, # <u>28</u> Exhibit AA, # <u>29</u> Exhibit BB, # <u>30</u> Exhibit CC, # <u>31</u> Exhibit DD, # <u>32</u> Exhibit EE, # <u>33</u> Exhibit FF, # <u>34</u> Exhibit GG, # <u>35</u> Exhibit HH, # <u>3</u> Exhibit II)(Kenney, Cortelyou) (Entered: 05/29/2018)
05/29/2018	<u>91</u>	COUNTER STATEMENT TO <u>71</u> Rule 56.1 Statement. Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 05/29/2018)
05/29/2018	<u>92</u>	RULE 56.1 STATEMENT. Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 05/29/2018)
05/29/2018	<u>93</u>	MOTION to Strike Document No. <u>72</u> Declaration of Ian Estepan. Document filed by Charles Seife.(Kenney, Cortelyou) (Entered: 05/29/2018)
05/29/2018	94	MEMORANDUM OF LAW in Support re: <u>93</u> MOTION to Strike Document No. <u>72</u> <i>Declaration of Ian Estepan.</i> . Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 05/29/2018)
06/11/2018	<u>95</u>	CONSENT LETTER MOTION for Extension of Time to File <i>Opposition to Motion to Strike & Summary Judgment Opposition/Reply</i> addressed to Judge Jesse M. Furman from Dominika Tarczynska & Kristen Ittig dated June 11, 2018. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 06/11/2018)
06/12/2018	96	ORDER granting <u>95</u> Letter Motion for Extension of Time to File. Defendants and Defendant–Intervenors are granted until July 30, 2018 to respond to (1) Plaintiff's motion to strike (Docket No. <u>93</u>), and (2) Plaintiff's cross–motion for summary judgment and reply in support of motions for summary judgment. Defendants and Defendant–Intervenors shall each file no more than one brief – that is, a consolidated brief in opposition and reply, as applicable. Further requests for extensions are unlikely to be granted. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 06/12/2018)
07/11/2018	<u>97</u>	FILING ERROR – DEFICIENT DOCKET ENTRY – FIRST MOTION for Margaret Elanor McCarthy to Withdraw as Attorney . Document filed by Charles Seife.(McCarthy, Margaret) Modified on 7/24/2018 (db). (Entered: 07/11/2018)
07/16/2018	<u>98</u>	MEMO ENDORSEMENT granting <u>97</u> Motion to Withdraw as Attorney. ENDORSEMENT: Application GRANTED. The Clerk of Court is directed to terminate Margaret E. McCarthy as counsel and to terminate Docket No. 97. SO ORDERED. Attorney Margaret Elanor McCarthy terminated. (Signed by Judge Jesse M. Furman on 7/16/2018) (ne) (Entered: 07/16/2018)
07/30/2018	<u>99</u>	REPLY MEMORANDUM OF LAW in Support re: 74 MOTION for Summary Judgment . & Opposition to Plaintiff's Cross—Motion for Summary Judgment & Opposition to Plaintiff's Motion to Strike. Document filed by Department Of Health and Human Services, Food and Drug Administration. (Tarczynska, Dominika) (Entered: 07/30/2018)
07/30/2018	<u>100</u>	DECLARATION of Howard R. Philips in Support re: <u>74</u> MOTION for Summary Judgment Document filed by Department Of Health and Human Services, Food and Drug Administration. (Attachments: # <u>1</u> Exhibit 1)(Tarczynska, Dominika) (Entered: 07/30/2018)
07/30/2018	101	RESPONSE in Opposition to Motion re: <u>69</u> MOTION for Summary Judgment ., <u>85</u> CROSS MOTION for Summary Judgment . <i>Sarepta Therapeutics, Inc.'s Response in</i>

		Opposition to Plaintiff's Motion for Summary Judgment and Reply in Further Support of its Motion for Summary Judgment. Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 07/30/2018)
07/30/2018	<u>102</u>	MEMORANDUM OF LAW in Opposition re: <u>93</u> MOTION to Strike Document No. <u>72</u> Declaration of Ian Estepan. Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 07/30/2018)
07/30/2018	<u>103</u>	COUNTER STATEMENT TO <u>92</u> Rule 56.1 Statement. Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 07/30/2018)
07/30/2018	<u>104</u>	RESPONSE to Motion re: 69 MOTION for Summary Judgment ., 85 CROSS MOTION for Summary Judgment . Declaration of Amanda Sherwood in further support of Sarepta's Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment. Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 07/30/2018)
07/30/2018	105	RESPONSE to Motion re: <u>93</u> MOTION to Strike Document No. <u>72</u> Declaration of Ian Estepan., <u>69</u> MOTION for Summary Judgment., <u>85</u> CROSS MOTION for Summary Judgment . Declaration of Ian Estepan in further support of Sarepta's Motion for Summary Judgment, in opposition to Plaintiff's Motion for Summary Judgment, and in opposition to Plaintiff's Motion to Strike. Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 07/30/2018)
08/09/2018	<u>106</u>	NOTICE OF CHANGE OF ADDRESS by Cortelyou Churchill Kenney on behalf of Charles Seife. New Address: Cornell Law School, First Amendment Clinic, Myron Taylor Hall, Ithaca, NY, United States 14853, (607) 255–8897. (Kenney, Cortelyou) (Entered: 08/09/2018)
08/09/2018	<u>107</u>	NOTICE OF CHANGE OF ADDRESS by David A. Schulz on behalf of Charles Seife. New Address: Ballard Spahr LLP, 1675 Broadway, 19th Floor, New York, NY, USA 10019, 212–850–6103. (Schulz, David) (Entered: 08/09/2018)
08/09/2018	<u>108</u>	LETTER MOTION for Extension of Time <i>to File Reply</i> addressed to Judge Jesse M. Furman from David A. Schulz dated August 9, 2018. Document filed by Charles Seife.(Schulz, David) (Entered: 08/09/2018)
08/09/2018	109	ORDER granting 108 Letter Motion for Extension of Time. Plaintiff's request for an extension is granted. The deadline for Plaintiff's Reply is now August 30, 2018. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 08/09/2018)
08/24/2018	110	ORDER: With respect to each of the motions filed in this case (i.e., the parties' motions and cross—motions for summary judgment and Plaintiff Charles Seife's Motion to Strike), the parties shall (1)submit paper courtesy copies of their briefs (but only their briefs) and (2) electronic courtesy copies of all materials in accordance with the following procedures. No later than September 7, 2018, the moving party shall submit electronic courtesy copies of all motion papers in electronic folders titled with the docket number of the relevant motion in brackets followed by a description of the motion (e.g., "500 Plaintiff's Cross—Motion for Summary Judgment"). The folder shall contain: 1. Unredacted, text—searchable PDFs of (1) any pleading to which the motion relates (e.g., the operative complaint); (2) the notice of motion; and (3) the moving, opposition, and reply memoranda of law, each of which should be named with the docket number of the document in brackets followed by a description of the file (e.g., "501 Plaintiff's Memorandum of Law in Support"); 2. A subfolder for each set of corresponding supporting documents titled with the docket number associated with the related memorandum of law, followed by (as appropriate) "Motion Documents," "Opposition Documents," or "Reply Documents," each of which shall contain: a. Unredacted, text—searchable PDFs of any and all corresponding supporting documents (e.g., Local Rule 56.1 Statements, declarations, affidavits, and affirmations), with any exhibits not filed under seal attached as part of the same PDF, each of which should be named with the docket number of the document (or the docket number of the corresponding document in the case of documents filed under seal or in redacted form) in brackets followed by a description of the file (e.g., "504 Declaration of Brent Roberts"); and b. A sub—sub—folder containing unredacted, text—searchable PDFs of any exhibits to a supporting document, including any documents that were filed under seal or in redacted form, each of whic

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		number of the corresponding document in brackets followed by "Sealed Exhibits to [LAST NAME] [Declaration/Affirmation/Affidavit]" (e.g., " 504 Sealed Exhibits to Roberts Declaration"). The names of the exhibits within the sub–sub–folder should correspond to the exhibit number (e.g., "Exhibit 1," "Exhibit 2," etc.), and need not include a description of the exhibit; and as further set forth in this order. (Signed by Judge Jesse M. Furman on 8/24/2018) (ne) Modified on 8/24/2018 (ne). Modified on 8/27/2018 (ne). Modified on 8/27/2018)
08/27/2018	111	NOTICE OF APPEARANCE by Mark Howard Jackson on behalf of Charles Seife. (Jackson, Mark) (Entered: 08/27/2018)
08/30/2018	112	REPLY to Response to Motion re: <u>93</u> MOTION to Strike Document No. <u>72</u> <i>Declaration of Ian Estepan.</i> , <u>85</u> CROSS MOTION for Summary Judgment Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 08/30/2018)
08/30/2018	<u>113</u>	DECLARATION of Dr. Peter Lurie in Support re: <u>112</u> Reply to Response to Motion. Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 08/30/2018)
08/30/2018	114	DECLARATION of Charles Seife in Support re: 112 Reply to Response to Motion. Document filed by Charles Seife. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E)(Kenney, Cortelyou) (Entered: 08/30/2018)
08/30/2018	<u>115</u>	LETTER addressed to Judge Jesse M. Furman from Cortelyou C. Kenney dated August 30, 2018 re: Request for Oral Argument. Document filed by Charles Seife.(Kenney, Cortelyou) (Entered: 08/30/2018)
09/12/2018	<u>116</u>	NOTICE OF APPEARANCE by Christopher John Morten on behalf of Charles Seife. (Morten, Christopher) (Entered: 09/12/2018)
09/24/2018	117	LETTER addressed to Judge Jesse M. Furman from Cortelyou C. Kenney dated September 24, 2018 re: Request to Supplement the Record. Document filed by Charles Seife.(Kenney, Cortelyou) (Entered: 09/24/2018)
09/28/2018	<u>118</u>	NOTICE OF APPEARANCE by Peter Max Aronoff on behalf of Department Of Health and Human Services, Food and Drug Administration. (Aronoff, Peter) (Entered: 09/28/2018)
10/18/2018	<u>119</u>	RESPONSE re: <u>117</u> Letter . Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 10/18/2018)
10/18/2018	120	FILING ERROR – DEFICIENT DOCKET ENTRY – MOTION for Daniel L. Tobey to Withdraw as Attorney . Document filed by Charles Seife. (Attachments: # <u>1</u> Affirmation)(Leatherbury, Thomas) Modified on 11/16/2018 (ldi). (Entered: 10/18/2018)
10/18/2018	121	ORDER granting 120 Motion to Withdraw as Attorney. The Clerk of Court is directed to terminate Attorney Daniel L. Tobey as counsel. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) Transmission to Docket Assistant Clerk for processing. (Entered: 10/18/2018)
10/25/2018	122	TRANSCRIPT of Proceedings re: CONFERENCE held on 7/11/2017 before Judge Jesse M. Furman. Court Reporter/Transcriber: Jerry Harrison, (212) 805–0300. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Redaction Request due 11/15/2018. Redacted Transcript Deadline set for 11/26/2018. Release of Transcript Restriction set for 1/23/2019.(McGuirk, Kelly) (Entered: 10/25/2018)
10/25/2018	123	NOTICE OF FILING OF OFFICIAL TRANSCRIPT Notice is hereby given that an official transcript of a CONFERENCE proceeding held on 7/11/17 has been filed by the court reporter/transcriber in the above–captioned matter. The parties have seven (7) calendar days to file with the court a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript may be made remotely electronically available to the public without redaction after 90 calendar days(McGuirk, Kelly) (Entered: 10/25/2018)
11/15/2018	124	ORDER: The Court does not appear to have received courtesy hard copies of Docket Nos. 76, 76–1, 77, 77–1 to 77–15, 87, 88, 89, 90, 90–1 to 90–36, 94, 100, 102, 112,

		113, 114, 114–1 to 114–5, as required by Individual Rule 3(F). The parties are ordered to deliver one courtesy copy of each document (one copy in total, not from each party) to the Court as soon as possible and no later than Monday, November 19, 2018. SO ORDERED. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) (Entered: 11/15/2018)
12/27/2018	<u>125</u>	STANDING ORDER M10–468 The United States Attorney's Office shall notify the Court immediately upon the restoration of Department of Justice funding. (As further set forth in this Order.) (Signed by Judge Colleen McMahon on 12/27/2018) (ks) (Entered: 01/02/2019)
12/27/2018		Case Stayed (ama) (Entered: 01/14/2019)
01/15/2019	<u>126</u>	FILING ERROR – DEFICIENT DOCKET ENTRY – MOTION for Jean Hee Kim to Withdraw as Attorney . Document filed by Charles Seife. (Attachments: # 1/2 Exhibit Kim Affirmation ISO Motion to Withdraw)(Morten, Christopher) Modified on 2/5/2019 (db). (Entered: 01/15/2019)
01/16/2019	127	ORDER granting 126 Motion to Withdraw as Attorney. The Clerk of Court is directed to terminate Attorney Jean Hee Kim as counsel. (HEREBY ORDERED by Judge Jesse M. Furman)(Text Only Order) (Furman, Jesse) Transmission to Attorney Services/Help Desk. Transmission to Docket Assistant Clerk for processing. Transmission to Office of the Clerk of Court for processing. (Entered: 01/16/2019)
02/14/2019	<u>128</u>	LETTER addressed to Judge Jesse M. Furman from Christopher Morten, Counsel for Plaintiff Charles Seife dated February 14, 2019 re: U.S. Supreme Court grant of certiorari in Food Marketing Institute v. Argus Leader Media, No. 18–481. Document filed by Charles Seife.(Morten, Christopher) (Entered: 02/14/2019)
03/27/2019	129	MEMORANDUM OPINION AND ORDER re: 93 MOTION to Strike Document No. 72 Declaration of Ian Estepan filed by Charles Seife, 69 MOTION for Summary Judgment filed by Sarepta Therapeutics, Inc, 85 CROSS MOTION for Summary Judgment filed by Charles Seife, 74 MOTION for Summary Judgment filed by Department Of Health and Human Services, Food and Drug Administration. Accordingly, Sarepta is ORDERED to re-review its redactions to the full FOIA production in accordance with this Memorandum Opinion and Order; to unredact any publicly available information; and to provide the revised redactions to the FDA. The FDA, in turn, is ORDERED to review the revised redactions to ensure they comply with this Memorandum Opinion and Order and to then provide the revised documents to Seife. Unless and until the Court orders otherwise, Sarepta and the FDA shall complete those tasks no later than June 26, 2019. Further, the parties shall promptly meet and confer in an effort to agree upon a proposed order establishing protocols (if appropriate) and rolling deadlines for the foregoing review. The parties shall submit any such proposed order (or competing orders) no later than April 3, 2019. Finally, within one week of (1) the June 26, 2019 deadline for the production of documents re-reviewed in accordance with this Memorandum Opinion and Order and (2) the Supreme Courts decision in Food Marketing Institute, whichever is later, the parties shall submit a joint letter addressing whether the Court should (a) require or allow the parties to submit supplemental briefs in connection with the summary judgment motions; (b) deny the current motions without prejudice to filing new motions; or (c) decide the current motions based on the existing submissions. In the meantime, given the wait for the Supreme Court, the current motions will be administratively terminated. The Clerk of Court is directed to terminate Docket Nos. 69, 74, 85, and 93. SO ORDERED. (Signed by Judge Jesse M. Furman on 3/27/2019) (ne) (Entered: 03/27/2019)
04/03/2019	130	PROPOSED ORDER. Document filed by Charles Seife. Related Document Number: 129. (Morten, Christopher) Proposed Order to be reviewed by Clerk's Office staff. (Entered: 04/03/2019)
04/04/2019		***NOTICE TO COURT REGARDING PROPOSED ORDER. Document No. 130 Proposed Order was reviewed and approved as to form. (km) (Entered: 04/04/2019)
04/04/2019	<u>131</u>	ORDER: By May 3, 2019, Defendants will re–review the narrative portions of Clinical Study Reports 201 and 202 challenged in Exhibit A to the Kenney Declaration, ECF No. 90–1, and will re–produce in un–redacted form any publicly available

		information. By May 31, 2019, Defendants will re–review the portions of the appendices to Clinical Study Report 201 challenged in Exhibit A to the Kenney Declaration, ECF No. 90–1, and will re–produce in un–redacted form any publicly available information. (As further set forth in this order) (Signed by Judge Jesse M. Furman on 4/4/2019) (ne) (Entered: 04/04/2019)
06/05/2019	<u>132</u>	JOINT LETTER MOTION for Extension of Time <i>to file revised redacted materials</i> addressed to Judge Jesse M. Furman from Kristen Ittig, Counsel for Sarepta dated 6/5/2019. Document filed by Sarepta Therapeutics, Inc. (Attachments: # 1 Text of Proposed Order Proposed Order)(Sherwood, Amanda) (Entered: 06/05/2019)
06/06/2019	133	CONSENT ORDER granting 132 Letter Motion for Extension of Time. It is hereby ORDERED as follows: By May 3, 2019, Defendants will re–review the narrative portions of Clinical Study Reports 201 and 202 challenged in Exhibit A to the Kenney Declaration, ECF No. 90–1, and will reproduce in un–redacted form any publicly available information. By May 31, 2019, Defendants will re–review the portions of the appendices to Clinical Study Report 201 challenged in Exhibit A to the Kenney Declaration, ECF No. 90–1, and will re–produce in un–redacted form any publicly available information. By August 2, 2019 or within one week of the Supreme Court's decision in Food Marketing Institute, whichever is later, the parties shall submit a joint letter addressing whether the Court should (a) require or allow the parties to submit supplemental briefs in connection with the summary judgment motions; (b) deny the current motions without prejudice to filing new motions; or (c) decide the current motions based on the existing submissions. (As further set forth in this order) The Clerk of Court is directed to terminate Docket No. 132. SO ORDERED. (Signed by Judge Jesse M. Furman on 6/6/2019) (ne) (Entered: 06/06/2019)
07/10/2019	<u>134</u>	CONSENT LETTER MOTION for Extension of Time <i>regarding July 12, 2019 Production Deadline</i> addressed to Judge Jesse M. Furman from Dominika Tarczynska dated July 10, 2019. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 07/10/2019)
07/10/2019	<u>135</u>	ORDER granting 134 Letter Motion for Extension of Time. Defendants' request is GRANTED; the deadline to review those documents and produce publicly available information in unredacted form is EXTENDED to July 19, 2019. The Clerk of Court is directed to terminate Docket No. 134. SO ORDERED. (Signed by Judge Jesse M. Furman on 7/10/2019) (ne) (Entered: 07/10/2019)
08/01/2019	<u>136</u>	JOINT LETTER addressed to Judge Jesse M. Furman from Dominika Tarczynska dated August 1, 2019 re: Proposed Schedule for Supplemental Summary Judgment Briefing. Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 08/01/2019)
08/02/2019	137	MEMO ENDORSEMENT on re: 136 Letter, filed by Department Of Health and Human Services, Food and Drug Administration. ENDORSEMENT: SO ORDERED. That said, to simplify things (i.e., to ensure that the Court won't need to refer to two sets of briefs and figure out what portions of the prior briefs are still relevant as opposed to moot), the parties' "supplemental" motion papers should incorporate any and all arguments from their prior briefing that remain relevant. In other words, the parties' "supplemental" motions should stand on their own and should not incorporate by reference arguments made in the earlier briefing. (Motions due by 9/30/2019, Replies due by 12/23/2019.) (Signed by Judge Jesse M. Furman on 8/2/2019) (ne) Modified on 10/9/2019 (ne). (Entered: 08/02/2019)
08/02/2019		Set/Reset Deadlines: Cross Motions due by 11/4/2019. Responses due by 12/5/2019. (ne) (Entered: 10/09/2019)
08/19/2019	<u>138</u>	NOTICE OF CHANGE OF ADDRESS by Christopher John Morten on behalf of Charles Seife. New Address: New York University School of Law, 245 Sullivan Street, 5th Floor, New York, NY, United States 10012, 212 998 6430. (Morten, Christopher) (Entered: 08/19/2019)
09/30/2019	<u>139</u>	MOTION for Summary Judgment (Notice of Defendant–Intervenor Sarepta Therapeutics, Inc.'s Renewed Motion for Summary Judgment). Document filed by Sarepta Therapeutics, Inc.(Bernstein, Daniel) (Entered: 09/30/2019)

09/30/2019	<u>140</u>	MEMORANDUM OF LAW in Support re: 69 MOTION for Summary Judgment ., 139 MOTION for Summary Judgment (Notice of Defendant-Intervenor Sarepta Therapeutics, Inc.'s Renewed Motion for Summary Judgment) Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 09/30/2019)
09/30/2019	<u>141</u>	RULE 56.1 STATEMENT. Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 09/30/2019)
09/30/2019	<u>142</u>	DECLARATION of William J. Thornton in Support re: <u>69</u> MOTION for Summary Judgment ., <u>139</u> MOTION for Summary Judgment (<i>Notice of Defendant–Intervenor Sarepta Therapeutics, Inc.'s Renewed Motion for Summary Judgment</i>) Document filed by Sarepta Therapeutics, Inc. (Bernstein, Daniel) (Entered: 09/30/2019)
09/30/2019	143	DECLARATION of Christopher Verni in Support re: 69 MOTION for Summary Judgment ., 139 MOTION for Summary Judgment (Notice of Defendant–Intervenor Sarepta Therapeutics, Inc. 's Renewed Motion for Summary Judgment) Document filed by Sarepta Therapeutics, Inc. (Attachments: # 1 Attachment)(Bernstein, Daniel) (Entered: 09/30/2019)
09/30/2019	144	DECLARATION of Amanda Sherwood in Support re: <u>69</u> MOTION for Summary Judgment ., <u>139</u> MOTION for Summary Judgment (<i>Notice of Defendant–Intervenor Sarepta Therapeutics, Inc.'s Renewed Motion for Summary Judgment</i>) Document filed by Sarepta Therapeutics, Inc. (Attachments: # <u>1</u> Attachment)(Bernstein, Daniel) (Entered: 09/30/2019)
09/30/2019	<u>145</u>	MOTION for Summary Judgment <i>Notice of Renewed Motion for Summary Judgment</i> . Document filed by Department Of Health and Human Services, Food and Drug Administration.(Tarczynska, Dominika) (Entered: 09/30/2019)
09/30/2019	<u>146</u>	MEMORANDUM OF LAW in Support re: <u>145</u> MOTION for Summary Judgment <i>Notice of Renewed Motion for Summary Judgment</i> . Document filed by Department Of Health and Human Services, Food and Drug Administration. (Tarczynska, Dominika) (Entered: 09/30/2019)
11/04/2019	<u>147</u>	CROSS MOTION for Summary Judgment . Document filed by Charles Seife. Responses due by 12/5/2019(Kenney, Cortelyou) (Entered: 11/04/2019)
11/04/2019	<u>148</u>	MEMORANDUM OF LAW in Support re: 147 CROSS MOTION for Summary Judgment . and in Opposition to Defendants' Motions for Summary Judgment. Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 11/04/2019)
11/04/2019	<u>149</u>	DECLARATION of Charles Seife in Support re: <u>147</u> CROSS MOTION for Summary Judgment Document filed by Charles Seife. (Attachments: # <u>1</u> Exhibit Attachment A)(Kenney, Cortelyou) (Entered: 11/04/2019)
11/04/2019	<u>150</u>	DECLARATION of Dr. Peter Lurie in Support re: <u>147</u> CROSS MOTION for Summary Judgment Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 11/04/2019)
11/04/2019	<u>151</u>	DECLARATION of Dr. Diana Zuckerman in Support re: <u>147</u> CROSS MOTION for Summary Judgment Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 11/04/2019)
11/04/2019	<u>152</u>	RULE 56.1 STATEMENT. Document filed by Charles Seife. (Kenney, Cortelyou) (Entered: 11/04/2019)
11/04/2019	153	DECLARATION of Cortelyou C. Kenney in Support re: 147 CROSS MOTION for Summary Judgment Document filed by Charles Seife. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J, # 11 Exhibit K, # 12 Exhibit L, # 13 Exhibit M, # 14 Exhibit N, # 15 Exhibit O, # 16 Exhibit P, # 17 Exhibit Q, # 18 Exhibit R, # 19 Exhibit S, # 20 Exhibit T, # 21 Exhibit U, # 22 Exhibit V, # 23 Exhibit W, # 24 Exhibit X1, # 25 Exhibit X2, # 26 Exhibit Y, # 27 Exhibit Z, # 28 Exhibit AA, # 29 Exhibit BB, # 30 Exhibit CC, # 31 Exhibit DD, # 32 Exhibit EE, # 33 Exhibit FF, # 34 Exhibit GG, # 35 Exhibit HH, # 36 Exhibit II, # 37 Exhibit JJ, # 38 Exhibit KK, # 39 Exhibit LL)(Kenney, Cortelyou) (Entered: 11/04/2019)